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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,003	10/26/2000	M. Rigdon Lentz	LEN 101 CIP CON	7721

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EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/01/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/699,003

Applicant(s)

LENTZ, M. RIGDON

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-10,12 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-10,12 and 16-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 24 January 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

1. Applicant cancelled claims 7, 11, 13-15, & 21-29. Therefore, the rejections under 35 USC 112, first and second paragraphs, have been withdrawn.

Applicant has amended claims 1, 8, and 12.

The changes to the drawing to indicate a column have been approved. The drawing objection has been withdrawn.

***Response to Arguments***

2. Applicant's arguments with respect to claims 1-6, 8-10, 12, & 16-20 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 8, 12, ~~14~~ and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lentz (4,708,713) in view of Selinsky et al. ("*Multifaceted inhibition of anti-tumor immune mechanism by soluble tumour necrosis factor receptor type I*").

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Lentz discloses a method and system for inducing an immune response against diseases and conditions that result from or are dependent upon deficiencies in the immune response system. Lentz teaches that immunosuppressive components are removed from the body until the level of immunosuppressive components in the body are reduced to a level which cause an acute immune response against the disease or condition. Such diseases or conditions can be cancer or neoplastic tissue (i.e. a tumor). The system includes a filter, inlet and outlet means for connection to a pump, tubing for fluid delivery and return, and a syringe pump (col. 3, lines 56-68). Lentz's method comprises withdrawing blood from a patient, extracorporeally treating the blood to selectively separate the components having a low molecular weight, and returning the treated blood to the patient, which will inherently initiate an immune response against the disease or condition the patient is suffering from. The blood is treated by passing through a filter that removes the immunosuppressive components from the blood. Lentz also discloses that the treatment is carried out on multiple occasions. With respect to claim 20, the recitation of "wherein the blood is plasma" has not been given patentable weight because it is narrative in form. In order to be given patentable weight, a functional recitation must be expressed as "means" for performing the specified function, as set forth in 35 USC § 112, 6<sup>th</sup> paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language (In re Fuller). Therefore, the tubing in the system of Lentz is clearly capable of circulating plasma through the tubing. With respect to claim 5, the method and

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system of Lentz including treating the tissue multiple therapies in methods of treating cancer was well known in the art at the time of the invention.

Selinsky et al. ("*Multifaceted inhibition of anti-tumor immune mechanism by soluble tumour necrosis factor receptor type I*") teaches of a procedure to remove soluble tumor necrosis factor receptor type I (TNFR1), which is a biological component that inhibits or blocks immunological mechanisms in tumor cell eradication, by ultrapheresis as a treatment for cancer immunotherapy. The removal of TNFR1 allows tumor necrosis factor (TNF), which induces cell death (apoptosis), to circulate in the body and destroy the tumor cells.

Lentz teaches of the removal of "immunosuppressive components" from the blood of a patient. The TNFR1 is seen to be equivalent to said component since it suppresses a natural immunological component, TNF, from performing its function. At the time of the invention, it would have been obvious to one having skill in the art to modify the method of Lentz to select TNFR1 as the soluble cytokine receptor molecule to be removed in order to enhance the death of tumor cells in cancer patients and improve the patient's own immune response against the tumor.

4. Claims 9, 10 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz & Selinsky in view of Okarma et al. (5,523,096). Lentz & Selinsky discloses the invention substantially as claimed, see rejection supra. Lentz & Selinsky, however, fails to disclose specifically the device being an absorbent column for removing cytokines or TNF from the blood wherein the column has immobilized

cytokine fragments through which blood is passed. Okarma et al. discloses an extracorporeal system for removing cytokines from the blood, such as TNF, using an absorption matrix in a column (see col. 3, line 28-col. 4, line 14 & fig. 1B). At the time of the invention, it would have been obvious to combine Lentz and Okarma by substituting the absorbent column of Okarma for the device of Lentz since the removal of cytokines using said column performs an equivalent function, that of removing components from blood. Further, Okarma teaches that the removal of cytokines is done to control the immune system's response to diseases and provide lower circulating levels of cytokines in the blood of a patient.

5. Claim 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentz ('713) and Selinsky in further view of Wolpe (5,861,483). Lentz & Selinsky substantially disclose the invention as claimed, see rejection supra. Lentz also teaches of including a source of anticoagulant in the device. Lentz, however, fails to disclose specifically the agent selected from the group consisting of anti-angiogenic compounds, procoagulant compounds, cytokines, chemotherapeutic agents, and radiation in dosage formulation.

Wolpe, however, discloses the need for stimulatory cytokines, especially erythropoietin, to maintain a fully functional immune system. The methodology that Lentz's method is based on is removing immune inhibitors and letting the body's immune system combat the disease. Therefore, it would have been obvious to a person skilled in the art to add erythropoietin to Lentz's system since erythropoietin works towards maintaining a fully functional immune system (col. 1, lines 25-45). To

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one of ordinary skill in the art, it would have been obvious to replace the erythropoietin with one of the above listed agents since it has been held to be within the general skill of a worker in the art, such as the physician in charge of the patient's care, to select a known agent or compound on the basis of its suitability for the treatment being performed. In re Leshin, 125 USPQ 416.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

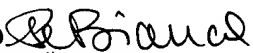
7. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone

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number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays from 9:00 AM until 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco  
Patent Examiner  
Art Unit 3762

pmb   
July 30<sup>th</sup>, 2003